UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,569	02/27/2008	Karin Klokkers	930008-2208	6210

26259 7590 07/22/2010

LICATA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER	
ALAWADI, SARAH	
ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
07/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/577,569	KLOKKERS ET AL.	
	Examiner	Art Unit	
	SARAH AL-AWADI	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-57,60 and 61* is/are pending in the application.

4a) Of the above claim(s) *37,39,46 and 48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-36,38,40-45,47,52-57 and 60-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/27/2006, 05/28/2009 and 01/08/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

INFORMATION DISCLOSURE STATEMENTS

The IDS submitted on 04/27/2006, 05/28/2009 and 01/08/2010 have been acknowledged.

RESPONSE TO REMARKS OVER SPECIES ELECTION

Applicant's election with traverse of the species polyacrylates as the film forming polymer, magnesium stearate as the salt, pellets as the dosage form, and metoprolol as the type of drug in the reply filed on 06/08/2008 is acknowledged. The traversal is on the ground(s) that the species relate to a single general inventive concept, and do not present a serious search burden. Applicants further argue that the prosecution of each of the disclosed species separately will pose a substantial economic burden on Applicants. This is not found persuasive because search burden is not required for establishing lack of unity of invention. Furthermore, the MPEP does not disclose economic burden as a requirement for rejoining species elections.

Claims 37, 39, 46, 48-49, and 50-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/28/2010.

The requirement is still deemed proper and is therefore made FINAL.

OBJECTIONS

Claim 57 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Customary auxiliaries would necessarily be pharmaceutically acceptable auxiliaries.

Claim 32 is objected to because of the following informalities: The term "cased" is misspelled. It is believed that Applicants meant to recite "case." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants claim an active ingredient containing core of pellets. However, in claim 47 the active-ingredient core is inert with an active ingredient coating. If the active-ingredient core is inert, it is unclear how the active ingredient core is thus still "active." The Examiner interprets claims 45 and 47 in light of the specification (more specifically paragraphs 92-96) as being directed towards an inert core comprising active ingredients which coat the inert core.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-36, 38, 41,43-45,47,52, 53-55, 56-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Skinhoj et al. (USPgPub 2002/0034544). However, in the interest of efficiency in citing specific column and line numbers, the disclosure of US (7,070,803 (identical in disclosure to the PgPub) is cited below.

Skinhoj et al. teach coatings which are made by mixing a polyacrylate dispersion (Eudragit NE30D) with magnesium stearate (fatty acid salt) and silicates such as talc, see column 36 lines 1-20 and column 19, lines 59-66. In one embodiment the aqueous dispersion can include Eudragit NE 30D or a mixture of acrylic resins, including Eudragit RL 30D and Eudragit RS 30D, see column 19, lines 10-31. The coatings are applied by spraying using fluidized bed. Skinhoj et al. teach multi-layer coatings with an inert core containing layers of active ingredient (midodrine). The core can comprise of coated pellets, see example 12. The pellets can be provided in multiple-unite dosage systems within capsules, see Example 12. Binders such as microcrystalline cellulose (auxiliary) can be incorporated with the active ingredient, see column 35, example 12-1.

Claims 32-36, 38, 41,43-45,,47,52, 53-55, 56-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Mulye et al. United States Patent Application 2005/0129778.

Muyle et al. teach pharmaceutical coatings for beads, see abstract and paragraph 0017. Such coatings contain controlled release polymers and an inert core, see paragraph 0083. An inner layer contains the water-soluble drug and the outer contains a controlled release polymer, see paragraph 0083. The formulation may contain any other component mixed that is normally present in sustained release polymers, see paragraph 0083. Examples of polymers used with Muyle et al. include polyacrylates such as mixtures of acrylic acid and methacrylate polymers, see paragraph 0090. The polymer can be in the form of an aqueous dispersion, see paragraph 0090. The coating layers may contain additional components such as a mixture of magnesium stearate and silicates such as talc or kaolin, see paragraph 0097. The formulations of Muyle et al. are sprayed onto inert beads using fluid bed coating machines, see paragraph 0028. Mulye et al. teach that auxiliaries such as binders are present with the drug, see paragraph 0078. Examples of suitable water soluble drugs to be used include that of metoprolol tartate, see claim 109. Mulye et al. teach multiple unit dosage forms such as capsules containing beads (pellets), see paragraph 0098.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-36, 38, 41, 43-45,,47,52, 53-57 and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulye et al. United States Patent Application 2005/0129778 and Lofroth et al. United States Patent Application 2004/0030033.

Muyle et al. teach pharmaceutical coatings for beads, see abstract and paragraph 0017. Such coatings contain controlled release polymers and an inert core, see paragraph 0083. An inner layer contains the water-soluble drug and the outer contains a controlled release polymer, see paragraph 0083. The formulation may contain any other component mixed that is normally present in sustained release polymers, see paragraph 0083. Examples of polymers used with Muyle et al. include polyacrylates such as mixtures of acrylic acid and methacrylate polymers, see paragraph 0090. The polymer can be in the form of an aqueous dispersion, see paragraph 0090. The coating layers may contain additional components such as a mixture of magnesium stearate and silicates such as talc or kaolin, see paragraph 0097. The formulations of Muyle et al.

are sprayed onto inert beads using fluid bed coating machines, see paragraph 0028. Mulye et al. teach that auxiliaries such as binders are present with the drug, see paragraph 0078. Examples of suitable water soluble drugs to be used include that of metoprolol tartate, see claim 109. Mulye et al. teach multiple unit dosage forms such as capsules containing beads (pellets), see paragraph 0098. Regarding the amount of fatty acid salt present and the content of the layer silicate present it would have been within the purview of the skilled artisan to optimize the amounts of each component as MPEP 2144.05 recites, "where "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine optimization."

Mulye et al. does not expressly teach metoprolol or metoprolol succinate.

Lofroth et al. teach dispersions of acrylate polymers. To contain the best spraying conditions, the polymers (Eudragit) are mixed with anti-sticking agents such as talc or stearates, see paragraph 0008. The beads of Lofroth et al. may contain inert cores of silicon dioxide, which active ingredient is deposited, see paragraph 0042. The active ingredients include metorpolol and metorpolol succinate, see paragraph 0065-0066.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include metoprolol and metoprolol succinate into the formulations of Mulye et al. One would have been motivated to do so in view of Mulye et al. which teach incorporating active ingredients which include salts of metoprolol. There would have been a reasonable expectation of success because both Muyle et al. and Lofroth et al. teach the use of pharmaceutical ingredients including metoprolol salts such as metoprolol fumarate.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678. The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH AL-AWADI/
Examiner, Art Unit 1619

/Shanon A. Foley/
Primary Examiner, Art Unit 1619